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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---|--------------|----------------------|-----------------------|------------------|--|--|
| 10/748,443 | 12/30/2003 | Michael J. Christie | 1671-0287 | 2376 | | |
| | | | | EXAMINER | | |
| MAGINOT, MOORE & BECK, LLP CHASE TOWER | | | CUMBERLEDGE, JERRY L | | | |
| 111 MONUME SUITE 3250 | ENT CIRCLE | | ART UNIT PAPER NUMBER | | | |
| INDIANAPOL | IS, IN 46204 | • | 3733 | | | |
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| | | • | MAIL DATE | DELIVERY MODE | | |
| | • | | 07/19/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| \ | Application No. | Applicant(s) | | | | |
|--|--|--|--------|--|--|--|
| | 10/748,443 | CHRISTIE ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jerry Cumberledge | 3733 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence ad | ldress | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this c D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>04 M</u> | av 2007 | | | | | |
| | action is non-final. | | | | | |
| / | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| · | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-18 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) <u>16-18</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-15</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| | r | | | | | |
| 9)⊠ The specification is objected to by the Examiner. 10)⊠ The drawing(s) filed on <u>30 December 2003</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner. | | | | | | |
| | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Ex | • | • | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a |)-(d) or (f). | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents | s have been received. | • | | | | |
| 2. Certified copies of the priority documents | | | | | | |
| 3. Copies of the certified copies of the prior | rity documents have been receive | ed in this National | Stage | | | |
| application from the International Bureau | application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| | • | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date <u>09/02/2005</u> <u>01/24/2005</u> . | 6) Other: | . • | | | | |
| S. Patent and Trademark Office | ······································ | | | | | |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-15) in the reply filed on 05/04/2007 is acknowledged. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method for cutting a triangular cavity in bone, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/04/2007.

Drawings

The drawings are objected to because the drawings are blurry and indistinct. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application

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must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 1-15 are objected to because of the following informalities: Claims 1-15 contain language directed toward shafts (i.e. drive shaft, shaft). It is suggested that applicant names the shafts with distinct terms (i.e. drive shaft and frame shaft) to alleviate any ambiguity as to whether the shafts are the same shaft or different shafts.

Furthemore, the claims refer to brackets, and there are many brackets disclosed in Applicant's specification. It is suggested that applicant use the terms found in the

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specification (e.g. "shaft alignment bracket" or "guide tab bracket" or "miller cutter bracket" or bearing bracket, etc.) to alleviate any confusion as to which brackets the claims are referring to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, and 9, as best understood by the Examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US Pat. 5,919,195).

Wilson discloses an apparatus for creating a cavity in a bone, said cavity (i) having a cross section which has a generally triangular profile having a first side generally parallel with an axis of the bone and a second side forming an acute angle with the first side, and (ii) being contiguous with a pre-existing conical cavity in the bone, said apparatus comprising: a drive shaft (Fig. 5A, ref. 104) having an axis, a proximal end (Fig. 5A, end near ref. 102) configured for coupling to a drive means and a distal end (Fig. 5A, end near ref. 132) configured to form a portion of a drive joint for coupling the drive shaft to a cutter; a frame (Fig. 5A, ref. 166) for carrying a cutter (Fig. 5A), the frame including a shaft (Fig. 5A, ref. 108) having a longitudinal axis and a cutter mount (Fig. 5A, ref. 110) for mounting a cutter at a first angle approximating the acute angle with respect to the shaft, the mount including a bracket (Fig. 5A, near ref. 118 and 164)

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extending laterally from the shaft to a bearing (Fig. 5A, left of ref. 110) configured to receive a portion of a cutter and maintain the received cutter oriented at the first angle during rotation; a cutter (Fig. 5B, ref. 106 and associated shaft) for cutting said cavity, the cutter having a head (Fig. 5B) configured to form a portion of a drive joint for coupling the cutter to a drive shaft; and, wherein the drive shaft is coupled to the cutter to form the drive joint (Fig. 5B), the cutter is received in the mount at the first angle and the axis of the drive shaft forms a second angle with the longitudinal axis less than the first angle (Figs. 5A and 5B). The axis of the drive shaft is substantially parallel to the longitudinal axis of the shaft (Fig. 5A). The device further comprises a sleeve (Fig. 5A, ref. 132) disposed about portions of the drive shaft adjacent the cutter. The drive shaft and sleeve are mounted to the frame (Fig. 5A) to move relative thereto to facilitate loading and removal of a cutter. The device further comprises a plate (Fig. 5A, ref. 176) mounted substantially perpendicular to the longitudinal axis of the shaft and configured to transfer forces applied to the plate to the shaft. The device further comprises a miller shell (Fig. 5A, ref. 113) for registering the apparatus with the pre-existing conical cavity, the miller shell having a longitudinal axis (Fig. 5), an external surface (Fig. 5A), a portion of which engages the wall of the pre-existing conical cavity (Fig. 5A), and a shell (Fig. 5A, ref. 113) configured to receive the frame and allowing the frame to move along the longitudinal axis. The device further comprises indicators for indicating the longitudinal location of the miller frame relative to the miller shell (column 6, lines 45-55). The cutter comprises a cutting surface (Fig. 5B, distal portion of ref. 106) having an outer diameter and a bearing surface (Fig. 5B, proximal portion of ref. 106) at one end of the cutting

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surface having an outer diameter larger than the outer diameter of the cutting surface and wherein the bearing for receiving the cutter comprises a bearing surface (Fig. 5A, lower surface of ref. 110) for mating with said bearing surface of the cutter.

Claims 10-12, 14 and 15, as best understood by the Examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by DeCarlo, Jr. et al. (US Pat. 5,540,694).

DeCarlo, Jr. et al. discloses an apparatus for creating a cavity in a bone for receiving a prosthesis which has a conical portion and a projection of a generally triangular profile, said apparatus comprising: a shell (Fig. 4, ref. 26) comprising a conical portion (Fig. 4, portion near ref. 28) which defines a longitudinal axis (Fig. 4) and a shaft-receiving cavity (Fig. 4, ref. 46) for receiving a frame (Fig. 4, ref. 24); a frame (Fig. 4, ref. 24) having a shaft (Fig. 4, ref. 3), a drive shaft (Fig. 4, ref. 22) and a shield (Fig. 4, ref. 54), the shaft being received by the shaft-receiving cavity (Fig. 4) and being movable with respect to the shell along the longitudinal axis (Fig. 4), said frame configured to carry a cutter (Fig. 4, ref. 78) disposed at an acute angle relative to the longitudinal axis (Fig. 4), the drive shaft being disposed at an angle relative to the longitudinal axis less than the acute angle being configured at one end to couple to and drive the cutter and the shield being disposed about portions of the drive shaft adjacent the one end (Fig. 6); and a cutter (Fig. 4, ref. 78) for cutting a cavity having a generally triangular profile, said cutter being carried by said frame (Fig. 6) and being configured to mate with and be driven by the drive shaft. The cutter and the frame include mating bearing surfaces (Fig. 6, near ref. 56). The frame includes a bracket (Fig. 4, ref. 52) for

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maintaining the orientation of the drive shaft relative to the shaft. The cutter and the drive shaft are configured to cooperate to from a pinned-sleeve shaft coupling. The drive shaft includes a slotted end forming forks, since the threads of the shaft 78, Fig. 7 form slots and form forks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 7 and 8, as best understood by the Examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US Pat. 5,919,195) in view of Richelsoph (US Pat. 5,342,363).

Wilson et al. discloses the claimed invention except for the device further comprising a drive shaft bracket coupled to the frame and configured to receive the drive shaft therein and maintain the orientation of the axis of the drive shaft with respect to the longitudinal axis of the frame.

Richelsoph discloses an apparatus for creating a cavity in a bone (Fig. 6, ref. 38) that comprises a drive shaft bracket (Fig. 6, ref. 38) coupled to a frame (Fig. 6., ref. 34) and configured to receive a drive shaft therein (Fig. 6, ref. 84) and maintain the orientation of the axis of the drive shaft with respect to the longitudinal axis of the frame

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(Fig. 6). This bracket is useful in that it allows a cutting instrument to be placed through it in order resect a section of bone at a precise angle (column 3, lines 50-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the apparatus of Wilson et al. with the drive shaft bracket as taught by Richelsoph in order to allow a cutting instrument to be placed through it in order resect a section of bone at a precise angle (column 3, lines 50-61).

Claim 13, as best understood by the Examiner, is rejected under 35 U.S.C. 103(a) as being unpatentable over DeCarlo, Jr. et al. (US Pat. 5,540,694) in view of Halpern (US Pat. 5,468,243).

DeCarlo, Jr. et al. disclose the claimed invention except for the drive shaft being maintained in an orientation substantially parallel to the shaft.

Halpern discloses an apparatus for creating a cavity in a bone (Fig. 2, ref. 10) that comprises a frame (Fig. 2, ref. 10) that maintains a cutter (Fig. 2, ref. 34) at an orientation substantially parallel to the shaft of the frame (Fig. 2, ref. 46). This allows the device to provide a constantly-deepening exacavation or cavity in the superior neck of the femur, which is of a suitable depth and configuration for the insertion of a proximal flange or offset portion of an intramedullary femoral insert to inserted into the femur (column 7, lines 66-67)(column 8, lines 1-13).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the apparatus of DeCarlo, Jr. et al. with the frame maintaining the cutter at an orientation substantially parallel to the shaft of the

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frame as taught by Halpern et al. in order to allow the device of DeCarlo, Jr. et al. to provide a constantly-deepening exacavation or cavity in the superior neck of the femur, which is of a suitable depth and configuration for the insertion of a proximal flange or offset portion of an intramedullary femoral insert to inserted into the femur (column 7, lines 66-67)(column 8, lines 1-13).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

EDUARDO O ROBERT SUPERVISORY PATENT EXAMINER